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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,480	02/06/2004	Michel Dib	FRAV2003/0003 US NP	7069
5487	7590	05/27/2008		
ANDREA Q. RYAN SANOFI-AVENTIS U.S. LLC 1041 ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			EXAMINER KIM, JENNIFER M	
			ART UNIT 1617	PAPER NUMBER
			NOTIFICATION DATE 05/27/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPatent.E-Filing@sanofi-aventis.com
andrea.ryan@sanofi-aventis.com

Office Action Summary	Application No. 10/773,480	Applicant(s) DIB ET AL.	
	Examiner Jennifer Kim	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 8-20 is/are pending in the application.
- 4a) Of the above claim(s) 8-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed January 30, 2008 have been received and entered into the application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singer et al. (1973) in view of Tilkian (1978), all record.

Singer et al. teach 2-cyano-10-(2-methyl-3-(methyldamino)propyl)phenothiazine (also known as cyamemazine) is mainly indicated for the treatment of insomnia, psychomotor agitation, and delirium. (abstract). Singer et al. also teach that the cyamemazine is used as a sedative narcoleptic in the patient with psychiatric condition. (abstract).

Singer et al. do not expressly teach the treatment of obstructive sleep apnea and the specific amounts, the route of administration set forth set forth in claim 1 and the treatment of insomnia related to another mental disorder set forth in claim 4.

Tilkian teaches insomnia is a symptom of obstructive sleep apnea. (abstract).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ cyamemazine for the treatment of obstructive sleep apnea patients having insomnia because cyamemazine is effective in treatment of insomnia as taught by Singer et al. and because insomnia is a symptom of obstructive sleep apnea. One would have been motivated to make such a modification in order to successfully treat obstructive sleep apnea by treating the symptom of obstructive sleep apnea, insomnia that is effectively treatable with cyamemazine in view of Singer et al.

It would have been obvious to one of ordinary skill in the art to employ cyamemazine for the treatment of insomnia related to another mental disorder because Singer et al. teach that cyamemazine is mainly indicated for insomnia and delirium (mental disorder). Further, Singer et al. illustrate the administration of cyamemazine to psychiatric patients to achieve a sedative narcoleptic effect. One of ordinary skill in the art would have been motivated to employ cyamemazine to insomnia related to other disorders, particularly a disorder relating to mental status in order to achieve its main indicated effective treatment of both insomnia and mental disorder. There is a reasonable expectation of successfully treating insomnia related to another mental disorder because cyamemazine is useful for both disorders of insomnia and mental disorder and because Singer et al. demonstrates the actual administration of cyamemazine to psychiatric patients. The amounts of active agent to be employ set forth in claim 6 and the route of administration are all deemed obvious because Singer teaches the main indication of cyamemazine of treating insomnia and mental disorder, it is within the one of ordinary skill in the art to optimize the dosage and route of

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administration to be employed according to factors involving severity of condition being treated, the physical condition of the patient, the duration of treatment, the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier employed, the solubility of the formula therein and the dosage regimen desired for the composition and patient's preference. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ cyamemazine for the treatment of obstructive sleep apnea patients having insomnia because cyamemazine is effective in treatment of insomnia as taught by Singer et al. and because insomnia is a symptom of obstructive sleep apnea. One would have been motivated to make such a modification in order to successfully treat obstructive sleep apnea by treating the symptom of obstructive sleep apnea, insomnia that is effectively treatable with cyamemazine in view of Singer et al. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

None of the claims are allowed.

Response to Arguments

Applicants' arguments filed January 30, 2008 have been fully considered but they are not persuasive. Applicants argue that there is no teaching or suggestion

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whatsoever of the use of the cyamemazine in the treatment of insomnia or other sleep disorder such as sleep apnea nor is there even any indication in the Singer et al. that there is a reasonable expectation of successfully treating insomnia or sleep apnea alone with this compound. This is not found persuasive because Singer et al. teach that clinical effect of cyamemazine in actual patients for main indication including insomnia while Tilkian teaches insomnia is a symptom of obstructive sleep apnea. Therefore, it would have been obvious to one of ordinary skill in the art to employ cyamemazine for the treatment of insomnia or symptoms of insomnia caused by sleep apnea because the effectiveness of cyamemazine for the treatment of insomnia is well taught by Singer et al. and that the condition of having sleep apnea is presented with symptoms of insomnia as taught by Tilkian. One would have been motivated to treat insomnia exhibited by the sleep apnea disorder in order to alleviate the symptom of the sleep apnea thereby ultimately treat the sleep apnea by the treatment of the symptom.

Applicants argue that the amounts of active agent to be employed and the routes of administration are not obvious because singer et al. is silent in this regard. This is not found persuasive because The amounts of active agents to be used and the mode of administration, e.g. oral, or parenteral are all deemed obvious since they are all within the knowledge of the skilled pharmacologist. Further, Singer et al. teaches that cyamemazine is effective in treating insomnia. Therefore, the numeric effective amount is contemplated by the teaching that cyamemazine is clinically effective for the treatment of insomnia.

Applicants argue that the Examiner based on the rejection based on the patient population being treated in claim 5 is suffering from obstructive sleep apnea but it is admitted that the Singer et al. does not teach the treatment of obstructive sleep apnea. This is not found persuasive because Singer et al. do not expressly teach the treatment of obstructive sleep apnea. However, it would have been obvious to one of ordinary skill in the art to treat the obstructive sleep apnea by treating a symptom of obstructive sleep apnea such as insomnia in order to achieve an expected benefit of treating the symptoms of obstructive sleep apnea thereby alleviate the disease. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/
Primary Examiner, Art Unit 1617

Jmk
May 12, 2008